REMARKS

The remainder of this Reply is set forth under appropriate subheadings for the convenience of the Examiner.

Interviews with Examiners Winston and Coe

An Interview Summary, mailed from the U.S. Patent and Trademark Office on November 30, 2004, provided Examiner Winston's summary of the in-person interview conducted on November 17, 2004 between Examiner Winston, Sudhir V. Shah, M.D., the Applicant, and N. Scott Pierce and Mary K. Murray, Ph.D., Applicant's Attorneys. Applicant's Attorney notes that the date of the interview is mistakenly identified in the Interview Summary as November 16, 2004.

An Interview Summary, mailed from the U.S. Patent and Trademark Office on December 22, 2004, provided Examiner Winston's summary of the in-person interview conducted on December 14, 2004 between Examiners Winston and Coe, Sudhir V. Shah, M.D., N. Scott Pierce and Mary K. Murray, Ph.D.

The substance of the interviews concerned the Office Action mailed from the U.S. Patent and Trademark Office on September 10, 2004. All of the pending claims were discussed. Examiners Winston and Coe, Applicant and Applicant's Attorneys discussed the rejections under 35 U.S.C. § 112, first and second paragraphs. In particular, Applicant and Applicant's Attorneys directed Examiners Winston and Coe to portions of the specification that provided an adequate written description of the claimed invention and guidance and working examples for a method of treating microalbuminuria in a human by administering a dose of iron chelator. Applicant and Applicant's Attorney also discussed with Examiners Winston and Coe that the specification of the application enabled a person of skill in the art can make and use Applicant's claimed invention without undue experimentation. Further, in the interviews, Applicant presented additional data, supported by the application as filed and obtained subsequent to filing the application, that show that the administration of an iron chelator to a human having microalbuminuria treats the human. Examiners Winston and Coe requested that the additional data be provided in a Declaration Under 37 C.F.R. § 1.132 and stated that they would consider Applicant's arguments. Applicant is filing the requested Declaration with this Reply.

Amendments to the Specification

The specification was amended at page 5, line 13 to correct a typographical in the abbreviation for glomerulonephritis. Support for this amendment is found in the Figure.

The specification was amended at page 8, lines 13 and 15 to correct a typographical error in the designation of oxygen.

The specification was amended at page 17, line 28 to correct a self-evident typographical error in the description of the glomerular filtration rate. Support for this amendment is found in the specification, for example, at page 16, lines 17-20.

Table 1 was amended to correct a typographical error in the abbreviation of Henoch-Schonlein Purpura. Support for this amendment is found in Table 1, line 39.

No new matter is added in the amendments to the specification. Entry is requested.

Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which has not been described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The Examiner stated that Claim 1 is drawn to a genus of iron chelators and that the specification on page 10, lines 3-7 discloses the single species of an iron chelator, deferiprone. The Examiner further stated that there is substantial variability among the species of iron chelators. The Examiner directed Applicant to the Guidelines for the Examination of Patent Applications Under 35 U.S.C. § 112, first paragraph published in the Federal Register, Volume 66, No. 4, pages 1099-1111, Friday January 5, 2001 (hereinafter "Federal Register").

On page 1104, column 3, the Federal Register states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. ... Possession may be shown in a variety of ways including .... describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

On page 1105, column 3, the Federal Register states that possession may be shown in many ways including the following:

> An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics

As stated on page 1106, column 2, of the Federal Register:

> Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

On page 9, line 20 through page 21, line 6 of the specification, iron chelators are described as:

> An "iron chelator" refers to any molecule capable of interacting with iron, either Fe^{3+} or Fe^{2+}, to prevent the formation of catalytic iron from Fe^{3+} or to prevent, inhibit or interfere with iron (Fe^{3+} or Fe^{2+}) interacting, effecting or participating in the Haber-Weiss reaction or any other reaction which can generate hydroxyl radicals. The interaction between the iron chelator and iron, either Fe^{3+}, Fe^{2+}, or both, can be, for example, a binding interaction, an interaction as a result of steric hindrance or any reciprocal effect between iron and the iron chelator. The iron chelator can, for example, prevent the conversion of Fe^{3+} to Fe^{2+}, thereby indirectly preventing the reduction of hydrogen peroxide and formation of hydroxyl radicals in the Haber-Weiss reaction. Alternatively, or additionally, the iron chelator can interact directly with Fe^{2+} to prevent hydroxyl radical formation in, for example, the Haber-Weiss reaction.
>
> The iron chelator can be a peptide comprising natural or nonnatural (e.g., amino acids not found in nature) amino acids, polyethylene glycol carbamates, lipophilic or nonlipophilic polyaminocarboxylic acids, polyanionic amines or substituted polyaza compounds.

In addition, page 10, lines 7-16 identify a number of references that describe iron chelators. Iron chelators suitable for use in Applicant's claimed method are described in the specification by a number of identifying characteristics, physical properties, chemical properties and functional characteristics.

The specification provides a written description that conveys with reasonable clarity to those skilled in the art that Applicant was in possession of the claimed invention. Therefore, the specification meets the written description requirements of 35 U.S.C. § 112, first paragraph, as applied to Applicant's claimed invention, as set forth in Claim 1.

Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph. The Examiner stated that the specification, while enabling for a method for treating the kidney diseases of proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis does not enable a person in the art for a method of treating microalbuminuria in a human. The Examiner further stated that the specification has failed to provide guidance or working examples of treating microalbuminuria in a human by administering an iron chelator to a human suffering from microalbuminuria. In addition, the Examiner stated that the prior art at the time the invention was filed did not recognize a method of treating microalbuminuria in a human comprising administering iron chelators and, therefore, Applicant's claimed method is unpredictable.

The specification, at page 4, lines 21-26; page 5, lines 11-14; page 25, line 23 through page 28, line 4, and the Figure, describe a method of treating microalbuminuria in a human including methods to detect and diagnosis microalbuminuria and effective amounts of an iron chelator to restore the albumin levels in the human to levels before the human developed the microalbuminuria or to restore albumin levels to levels observed in a control individual. In addition, as noted by the Examiner, on page 4, line 21-26, and the accompanying Figure, the specification describes an increased catalytic iron content in the urine of humans with diabetic proteinuria, glomerulonephritis and ischemic nephropathy. Furthermore, Table 1, on page 37, and Table 2, on page 38 describe increased catalytic iron in the urine of humans having membranous nephropathy, systemic lupus erythematosus, focal segmental gomerulosclerosis, Henoch-

Schonlein Purpura, hemolytic uremic syndrome, membranoproliferative glomerulonephritis, chronic glomerulonephritis, ischemic nephropathy, diabetic nephropathy, microalbuminuria and diffuse proliferative glomerulonephritis. The specification provides guidance and numerous working examples of treating kidney conditions associated with an increase in catalytic iron in the urine, including microalbuminuria, by administering an iron chelator. Thus, Applicant has provided sufficient guidance and working examples to enable a person skilled in the art to make and use Applicant's claimed invention, as set forth in Claim 1.

The absence of Applicant's claimed invention in the prior art is evidence that Applicant's claimed method is novel and non-obvious, not that it is unpredictable. The wide variety of kidney diseases demonstrated by Applicant in the specification to correlate increased urinary catalytic iron with kidney disease provides guidance to a person skilled in the art to make and use Applicant's claimed method. The Examiner has presented no evidence that undue experimentation would be required for a person of skill in the art to practice Applicant's claimed invention.

In response to Examiner Winston's statement that the application does not contain any working examples of the claimed invention and at the request of Examiner Winston, Applicant encloses with this Reply a Declaration of Sudhir V. Shah, M.D., under 37 C.F.R. § 1.132 that describes data, supported by the application as filed and obtained subsequent to the filing of the application, showing that administration of an iron chelator to patients with microalbuminuria treats the patient. Dr. Shah is the Applicant and President of Shiva Biomedical, LLC, the assignee of the above-referenced application.

Dr. Shah states in his Declaration that, by employing the techniques and doses of iron chelators described in U.S. Application No: 10/820,537, the administration of an iron chelator to patients with microalbuminuria decreased the urinary protein in the patients. A decrease in urinary protein is an index of an improvement in kidney function and, thus, treatment of the microalbuminuria in the patients. Dr. Shah further states in his Declaration that there was a trend in a decrease in catalytic iron in the urine of patients with microalbuminuria undergoing treatment with the iron chelator. These additional data described by Dr. Shah in the Declaration show that by employing the techniques and doses of iron chelators described in U.S. Application No: 10/820,537, one of skill in the art can practice Applicant's claimed invention. Therefore, the

specification meets the enablement requirement of 35 U.S.C. §112, first paragraph, as applied to Applicant's claimed invention, as set forth in pending Claim 1.

SUMMARY AND CONCLUSION

The specification meets the requirements of 35 U.S.C. §112, first and second paragraphs. Therefore, Applicant respectfully requests reconsideration and allowance of the claims under consideration. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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